UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

MONROE EVANS and MATTIE EVANS,

Plaintiffs,

v.

ADVANCED BIONICS CORPORATION
28515 Westinghouse Place
Valencia, CA 91355

SERVE:
CSC-Lawyers Incorporating Service
2730 Gateway Oaks Dr., Ste. 100
Sacramento, CA 95833

And

ADVANCED BIONICS, LLC d/b/a
ADVANCED BIONICS CORPORATION
12740 San Fernando Road
Sylmar, CA 91342

SERVE:
Corporation Service Company
2711 Centerville Road, Ste. 400
Wilmington, DE 19808

Defendants.

CIVIL NO. 5:14-CV-376 (LEK/DEP)

COMPLAINT WITH
DEMAND FOR JURY TRIAL

Plaintiffs, Monroe Evans and Mattie Evans ("Plaintiffs), bring this action pursuant to applicable statutory and common law against Defendants Advanced Bionics Corporation and Advanced Bionics, LLC, and allege, upon information and belief, as follows:

SUMMARY OF THE ACTION

1. Monroe Evans ("Plaintiff") suffered from permanent hearing loss and will require a lengthy and risky open-head surgery as a result of the failure of an Advanced Bionics HiRes 90k medical device (the "Device") recalled by its manufacturer, Advanced Bionics. Upon information and belief, the device contained one or more manufacturing defects including but not limited to a component supplied by AstroSeal, Inc., and was, therefore, not in compliance with applicable federal law, including federal device manufacturing requirements.

2. Advanced Bionics violated the basic principal of biomedical engineering that moisture is to be avoided in electronic devices implanted in the human body. Advanced Bionics sold cochlear implants, medical devices used to provide a sense of sound to persons with profound hearing loss, which leaked. Advanced Bionics' specification for moisture content was 0.5%, yet Plaintiff's device apparently failed due to moisture far in excess of this limit. Water entered the Plaintiff's Advanced Bionics' HiRes90k implant through a leak in an AstroSeal manufactured critical component, causing device failure and which will require explantation and/or replacement surgery and other related damages.

3. The HiRes90k Device placed in the Plaintiff's head was designed, manufactured, and sold in violation of federal law and in violation of Advanced Bionics' federally-approved device specifications. It contained a latent defect not disclosed to the Food and Drug Administration ("FDA"), was adulterated, breached Advanced Bionics' express and implied warranties, and was defective and unreasonably dangerous for its intended use. Advanced Bionics was negligent in the design, manufacture and labeling of the Device and the AstroSeal component meant to provide a hermetic (waterproof) seal. Advanced Bionics knew or should have known that its devices were failing at an alarming and unacceptable rate as a result of moisture intrusion, had been cited by the FDA for violating federal manufacturing regulations, and yet Defendants continued to produce and promote defective devices with full knowledge

that it had not satisfactorily addresses or solved the moisture problems with its product. By October 2004 at the latest Advanced Bionics knew the HiRes 90K was defective, non-compliant, and leaking at the feed-thru yet did not advise clinicians or patients of the defect and allowed the continued surgical implantation of the device in unsuspecting patients with hearing disabilities. Advanced Bionics violated a host of federal regulations and state law, all of which Plaintiff makes a parallel claim for in this litigation. Advanced Bionics was reckless, placed profits above safety, endangered lives and senses, and intentionally engaged in unconscionable business practices by causing known defective devices to be surgically implanted into a disabled population.

4. The FDA filed an administrative enforcement action against Advanced Bionics and key employees for selling devices of the exact same type given to the Plaintiff because those devices were not FDA approved for sale in the United States and had been manufactured in violation of federal law. Advanced Bionics settled this FDA action, paying $1.1 million on behalf of the company and $75,000 on behalf of then-CEO Jeffrey Greiner, individually.

5. Defendants are liable to Plaintiffs for all consequential damages Plaintiffs have incurred as a result of injuries to the Plaintiff. Defendants are liable for the Plaintiffs pain, suffering, temporary and permanent hearing loss, revision surgeries, loss and/or delay in the Plaintiffs ability to articulate, and punitive damages. Defendants are liable for any and all other damages sustained by Plaintiffs.

PARTIES

6. Plaintiffs are adult resident citizens of Syracuse, Onondaga County, New York. Plaintiff received a cochlear implant in Syracuse, Onondaga County, New York, and is in the process of scheduling removal and replacement surgery for defendants' defective cochlear implant in Onondaga County, New York.

7. Plaintiff has suffered and will continue to suffer extensive damages in New York and in this district.

8. Defendant ADVANCED BIONICS CORPORATION is a California Corporation with its principal place of business at 28515 Westinghouse Place, Valencia, CA 91355.

9. Defendant ADVANCED BIONICS, LLC, is a Delaware Limited Liability Company with its principal place of business at 12740 San Fernando Road, Sylmar, CA 91342. Advanced Bionics, LLC, has done and continues to do business as Advanced Bionics Corporation and is a corporate successor to prior entities using the name "Advanced Bionics" for all purposes relevant to this Complaint subject to all liabilities relative to this Complaint attributable to a prior entity known as Advanced Bionics Corporation, a Delaware Corporation, that was at one time a wholly-owned subsidiary of BSC Scimed, Inc.

10. At all relevant times, Defendants were engaged in the business of, or were a successor in interest to entities engaged in the business of researching, developing, formulating, testing, manufacturing, producing, distributing, marketing, promoting (including direct-to-consumer advertising), packaging and selling hearing implant devices for use by individuals with hearing loss, including Plaintiff.

11. Each Defendant is individually, as well as jointly and severally, liable to Plaintiffs for damages.

VENUE

12. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a). The Plaintiffs are resident citizens of New York and the Defendants are foreign corporations, with their principal places of business and/or incorporations in California and/or Delaware.

13. The amount in controversy in this matter exceeds $75,000.00, exclusive of interest and costs.

14. Venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1391(a) and (c). Defendants regularly solicit and engage in business and other persistent courses of conduct and derive substantial revenues from goods used and consumed in New York and/or for services rendered in New York.

15. Defendants derive substantial revenue in New York from interstate commerce.

16. Defendants' HiRes90K was advertised (including direct-to-consumer advertising), provided and/or prescribed to, purchased and consumed by Plaintiff in Syracuse, Onondaga County, New York.

17. Defendants provided sales literature to medical facilities, audiology clinics, and clinicians in Syracuse, Onondaga County, New York, that was in turn provided to Plaintiffs and relied upon in the Plaintiffs decision to purchase Plaintiff's HiRes90K cochlear implant, provided technical and warranty support directly to Plaintiffs, and both directly and through Plaintiff's physician Defendants engaged in direct contact with Plaintiffs. Defendants' "VP, Regulatory Affairs" Cedrle Navarro communicated directly with the Plaintiff on November 14, 2013.

18. Defendants committed tortious acts within New York by promoting, marketing, distributing, retailing and selling the HiRes90K cochlear implant, a dangerous and defective medical device, to Plaintiff that proximately caused Plaintiff's injuries.

19. Defendants likewise failed to appropriately warn of the dangers of the HiRes90k to Plaintiff and Plaintiff's physicians, and similarly violated a host of federal regulations, all of which would have provided adequate notice to Plaintiff's physician and audiologist in New York, thereby preventing Plaintiff from receiving the Device.

20. Defendants expected or reasonably should have expected that their tortious acts would have consequences in New York.

GENERAL ALLEGATIONS

I. Cochlear implants are prosthetic hearing devices.

21. A cochlear implant is a Class III medical prosthesis designed to enable profoundly deaf persons to "hear" by directly stimulating auditory nerves leading to the brain by means of an electrode array strategically positioned in the cochlea of the inner ear.

22. Unlike hearing aids, cochlear implants do not amplify sound; instead, a miniature computer/sound processor, worn outside the body, selectively processes sound into coded signals. Such signals are transmitted by wireless electromagnetic conduction to an implantable cochlear stimulator (ICS) that is surgically implanted in the patient's body.

23. The ICS receives these coded signals and interprets them using its sophisticated microelectronic architecture to send specialized patterns of electrical current to the electrodes inserted inside of the cochlea. Multiple electrodes along the length of the electrode array emit electrical currents in the form of electrical stimulation pulses to the surrounding hearing nerve receptors based on scientific knowledge that different parts of the cochlear are sensitive to different sound frequencies. Nerve fibers then send this information to the brain for central processing, interpretation, and perception as sound.

24. Cochlear implant surgery requires general anesthesia and often involves a procedure called a mastoidectomy, in which an incision is cut and an indent is drilled into the skull to allow the attachment of the implant. Once the implant is attached, the electrode array is inserted in the delicate coiled cochlea of the inner ear by making a hole called a cochleonstomy and inserting the electrode array and threading it through as gently as possible to avoid trauma to the inner surfaces. Post-surgery vertigo and nausea are common. Paralysis of the facial nerves is a risk of surgery, as is tinnitus, cerebrospinal fluid leak, dizziness, loss of taste, bleeding, infection, scarring, worsening hearing, and damage to the vestibular system. The

surgery also carries the risks of major anesthesia including but not limited to malignant hyperthermia, cardiac arrest and death.

25. After surgery, initial programming of the external processor is not done until the incision has healed, which typically takes two to five weeks. At such initial stimulation and programming, the individual electrodes are programmed at appropriate threshold and amplitude levels based on the patient's response to stimulation, which is then used to create an electrode "map." Once all of the electrodes are mapped, the processor is turned on and the cochlear implant patient can "hear." This programming process continues to be fine-tuned at later appointments throughout the first year with the external processor eventually being programmed with multiple maps for different auditory environments.

26. In normal hearing, the cochlea is stimulated by hundreds of thousands of hair cells. The stimulation of the cochlea through implanted electrodes is very different. Thus a cochlear implant demands a long rehabilitation period in which the cochlear implant recipient's brain must learn how to decode and recognize sound.

27. The perception of sound by cochlear implant users is very different from normal hearing. Cochlear implant patients who have lost their hearing often describe the initial stimulation as hearing tiny "buzzes" and "whistles" that had no relation to what they remembered as sound and felt that they would never be able to comprehend.

28. Gradually through aural rehabilitation and listening experience, the brain may learn to decode sound. Over time, some cochlear implant recipients learn to distinguish sounds well enough so that they can talk on the telephone through the cochlear implant or listen to TV without closed-captioning.

29. When a defective cochlear implant is replaced, the electrode array may not be re-implanted in the same position in the cochlea, leading to different threshold and amplitude settings. As a result, rather than starting off by "hearing" at the comprehension level where the

defective implant failed, a cochlear implant patient may have to go through a second aural rehabilitation before the replacement implant functions at the same level as the first implant did.

30. There is no guarantee that a replacement cochlear implant will ever function at the same level as the first. In some cases, due to cochlea scarring or nerve damage from explant surgery, different electrode positioning, or other causes, a cochlear implant patient may not function as well with the replacement implant.

31. Different cochlear implant manufacturers use different sound strategies. Thus when a defective implant is replaced with a new device by a different cochlear implant manufacturer, an entire new sound system needs to be learned.

32. Revision, replacement and re-do surgeries of cochlear implants is anything but a simple or a straightforward procedure.

II. Moisture causes failure to cochlear implants.

33. Moisture is a well-known cause of failure of electronic circuits.

34. Moisture causes corrosion, dendrite growth, and other processes that damage electronic circuits and cause them to fail.

35. Implantable medical devices, such as cochlear implants, are exposed to more moisture than most electronic devices because the human body is a very wet and salty (saline) environment.

36. The human body is more than fifty percent (50%) water.

37. To function reliably electronic circuits inside cochlear implants are required to be clean, dry, and free of moisture.

38. Cochlear implants should remain dry and free of moisture vapor in excess of 0.5% to prevent harm to patients.

39. It is critical that a cochlear implant not allow moisture in, or any toxic compound out.

40. The failure of a cochlear implant requires surgery to remove and replace the failed implant.

41. Revision surgery risks include damage to the cochlea, cerebrospinal fluid leak, permanent loss of hearing, facial paralysis, bleeding, infection and other complications.

42. A revision surgery to explant and replace a cochlear implant can cause harm to a patient.

43. Moisture inside a cochlear implant may have been sealed in during the manufacturing process or may have leaked in at some point afterwards (including after the device was implanted in a patient), or both.

44. There is no other way moisture can enter the device.

45. A variety of techniques exist to determine the effectiveness of a seal (whether the seal is water proof or hermetic) of microelectronic devices with designed internal cavities. A designed internal cavity is the void space inside the device.

46. While a seal can be checked by a helium leak test, the helium leak test does not simulate the conditions of the human body.

47. Residual gas analysis ("RGA") is an analytical technique used primarily for hermeticity quality assurance and failure analysis purposes. In RGA, the test device is placed in a sealed chamber and punctured. The interior gases are sucked out and analyzed. The RGA can reveal, for example, the percentage of water vapor within a sealed medical device.

48. The RGA and other techniques to evaluate the hermeticity of a device may provide data to determine if, and why, a device leaked. Such techniques can also be used to determine if a device was properly assembled in the first place.

49. At all relevant times Advanced Bionics knew that federal law required its medical devices to be water proof, hermetically sealed, and devoid of excessive moisture content.

50. Device failure was well known to occur in a cochlear implant when the percentage of moisture vapor in a device is greater than 0.5%.

III. Advanced Bionics' HiResolution Cochlear Implant.

51. Advanced Bionics manufactured and sold a cochlear implant system referred to as the "HiResolution Bionic Ear System." The HiResolution system was marketed as an improved version of Advanced Bionics' former "CLARION Multi-Strategy Cochlear Implant." It was marketed as the HiRes90k.

52. The implant component of the system was the implantable cochlear stimulator (the "ICS").

53. The ICS consisted of, among with other parts, a "can," a sealed titanium metal housing containing an electronic circuit, an electrode (an insulated wire) that goes into and stimulates the cochlea, and an antenna to receive signals from the external processor.

54. The ICS included a feed-thru (also referred to as a feed through or feedthru) assembly. The feed-thru is designed to keep moisture from entering the implant and connects the electronic circuit inside the implant to the electrode through a water and gas proof fitting.

55. Advanced Bionics has used two different feed-thru suppliers on its HiRes90k cochlear implant device: Pacific Aerospace & Electronics, Inc. ("PA&E") and AstroSeal.

56. Both suppliers were supposed to provide interchangeable feed-thru assemblies meeting the same critical high standard of functionality and Advanced Bionics' specifications, including that the feed-thru provide a water proof and hermetic seal during the implant's anticipated 10-year life span.

57. Advanced Bionics added AstroSeal as a feed-thru supplier without receiving approval from FDA.

58. Advanced Bionics has admitted in its own documents that there were at least nine material differences in the AstroSeal feedthru, as compared to the PA&E feedthru.

IV. Federal Regulations.

59. One method of removing a class III medical device from the market is a recall. A recall should be the action taken by a manufacturer when a product is suspected of inflicting patient harm.

60. Under federal regulations, a "[r]ecall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure." 21 C.F.R. Part 7.3(g).

61. A device is deemed to be "adulterated" if, among other things, it fails to meet established performance standards, or if the methods, facilities, or controls used for its manufacture, packing, storage, or installation are not in conformity with federal regulations pursuant to 21 U.S.C. § 351 and 21 C.F.R. Part 820.1(c).

62. A device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular way, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

63. Advanced Bionics is required to comply with applicable FDA regulations, including FDA regulations relating to records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of its medical devices.

64. Adverse events associated with a medical device must be reported to FDA within 30 days after the manufacturer becomes aware that a device may have caused or contributed to death or serious injury, or that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the

manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. *See* 21 C.F.R. Part 803.50.

65. Manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to the FDA as a removal or correction of the device. *See* 21 C.F.R. Part 803.52.

66. Manufacturers must report to the FDA in five business days after becoming aware that a medical device reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. Medical device reportable events require the manufacturer to conduct a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to public health. *See* 21 C.F.R. Part 803.53.

67. Device manufacturers must report promptly to the FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of federal law caused by the device that may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. *See* 21 C.F.R. Part 806.10.

68. Pursuant to federal regulations, Current Good Manufacturing Practices ("CGMPs") require compliance with the following quality system regulations:

a. Manufacturers must meet design-control requirements, including without limitation, conducting design verification and validation to ensure that devices conform to defined use needs and intended uses;

b. Manufacturers must establish purchasing controls to ensure that all purchased products, parts and components conform to specified requirements;

c. Manufacturers must meet quality standards in manufacturing and production;

d. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions;

e. Manufacturers must investigate the cause of nonconforming product and take corrective action to prevent recurrence;

f. Manufacturers are required to review and evaluate all complaints and determine whether an investigation is necessary;

g. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance.

See generally 21 C.F.R. Park 820.

69. The CGMPs required that Advanced Bionics sufficiently evaluate and select AstroSeal as a supplier of feed-thru assemblies on the basis of its ability to meet specified device requirements, including quality requirements, related to its intended long-term use in the human body. 21 C.F.R. Part 820.50(a).

70. The CGMPs required that Advanced Bionics adequately validate all HiRes 90k devices by testing production lots under actual or simulated use conditions. 21 C.F.R. Part 820.30(g).

71. The CGMPs required Advanced Bionics to investigate the cause of moisture in its HiRes 90k implants and to take corrective action to prevent reoccurrences and to investigate clinical complaints from patients reporting erratic or non-functioning implants.

72. As stated above, a manufacturer's failure to comply with CGMPs applicable to a device renders the device adulterated under the FDCA, 21 U.S.C. § 351(h); 21 C.F.R. Part

820.1(c). Each introduction of an adulterated device into interstate commerce is a violation of the FDCA.21 U.S.C. § 331(a).

73. A device is deemed adulterated if the methods used in, and the facilities and controls used for, its manufacture, packing, storage, and installation are not in conformity with CGMP requirements. Each introduction of an. adulterated device into interstate commerce is a violation of federal law. 21 U.S.C. § 331(a).

V. Pre-Market Approval (PMA) Process.

74. FDA regulations require manufacturers to submit Pre-Market Approval Application ("PMA") supplements for changes that may affect the safety or effectiveness of a device, including "[t]he use of a different facility or establishment to manufacture" the device, and "[c]hanges in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device." 21 C.F.R. Part 814.39(a)(3) and (6). Such supplements are referred to as "180-day PMA supplements."

75. Any change in specifications of the materials used in manufacture requires a 180-day PMA supplement.

76. A manufacturer may make a change to a device without filing a PMA supplement **only** if the change does not affect the device's safety or effectiveness and the change is reported to FDA in post-approval periodic reports. 21 C.F.R. Part 814.39(b).

77. A feed-thru is a critical component and can affect the safety and/or effectiveness of a cochlear implant.

78. The former Director of Regulatory Affairs of Advanced Bionics (Kay Adair) testified in a deposition that a feedthru can affect the safety or effectiveness of a cochlear implant.

79. A device lacking necessary PMA approval (including approval of supplements) is deemed adulterated. 21 U.S.C. § 351(f)(1)(B).

80. Federal regulations require that a PMA supplement be submitted when unanticipated adverse effects increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification. *See* 21 C.F.R. Part 814.39.

81. Advanced Bionics first received PMA approval to manufacture cochlear implants for adults in 1996. The HiRes 90k was not approved as a separate Class III device, but was approved in the Thirtieth PMA supplement submitted by Advanced Bionics on July 7, 2003.

82. The July 2003 PMA listed as a "Conditions of Approval" that before Advanced Bionics made any changes affecting the safety or effectiveness of a device, it would submit a PMA supplement for review and approval by the FDA. This requirement in the July 2003 PMA was in accordance with FDA rules and regulations stating the same. *See* 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. Part 814.39(a).

83. Advanced Bionics was well aware of the PMA Supplement requirement. Not only was this requirement listed in all of Advanced Bionics' previously approved PMAs, but in 2001, the FDA had issued a List of Inspectional Observations ("Form FDA-483") related to an on-site inspection of Advanced Bionics' Sylmar, California facility related to hermeticity failure in an earlier model. In this FDA Form 483, the FDA listed Advanced Bionic's failure to file PMA supplements for four separate testing, manufacturing process, and design changes as violations of FDA regulations.

84. As part of the July 2003 HiRes 90k PMA, the FDA approved the design of the internal ICS of the HiRes 90k implant which was housed in a hermetically sealed (i.e. moisture-proof and airtight) titanium case attached to a critical component called the feed-thru assembly.

85. The feed-thru, as a component affecting the safety and functioning of the Advanced Bionics' HiRes 90k, performs the critical task of connecting the internal electronic

circuit board to the implanted electrodes through a series of pins which form the electrical path to the electrode array.

86. Equally important, the feed-thru assembly is designed to prevent internal body moisture from entering the implant by creating a hermetically (i.e.) water-proof and moisture proof barrier between the ICS internal circuitry and the electrodes. As such, the FDA approved specifications for the HiRes 90k which included the following:

a. that the HiRes 90k device would be "hermetically sealed" to prevent moisture intrusion such as blood;

b. that the HiRes 90k device would have a leak rate of less than 1 x 10^{-9} cc-atm/s of helium;

c. that the HiRes 90k device be 100% tested at the time of manufacture for hermeticity;

d. that the HiRes 90k device would contain no more than 0.500% (5,000 ppm) moisture; and

e. that the HiRes 90k and Clarion 1.2 devices be sealed with an inert gas mixture, 25% helium and 75% argon.

87. During the PMA approval process, Advanced Bionics submitted design data and documents relating only to the use of PA&E a/k/a Vendor A as the supplier of the critical feed-thru component.

88. After receiving the July 2003 PMA approval for the HiRes 90k based on only PA&E data, Advanced Bionic began using AstroSeal a/k/a Vendor B as a supplier of the HiRes 90k feed-thru.

89. The specifications of the AstroSeal feed-thru differed from the PA&E in at least nine ways, including but not limited to:

a. the composition of AstroSeal's glass seal was different, resulting in a different rate of thermal expansion in the glass;

b. there was a different mechanical configuration to support the ceramic bead of the AstroSeal feed-thru;

c. AstroSeal's feed-thru had a shorter glass seal;

d. the glass for the AstroSeal feed-thru was fired through a vacuum bake for a different length of time and at a different temperature than was approved in the July 2003 PMA; and

e. the thickness of the oxide layer was different.

90. Keith McLain, the Head of Quality at Advanced Bionics, wrote a report that outlined differences in the PA&E (vendor A) and AstroSeal (vendor B) feed-thru.

91. The change in using AstroSeal as a feed-thru supplier affected the safety and effectiveness of the HiRes 90k, yet Advanced Bionics neither filed a 180-Day PMA Supplement nor a 30-Day Notice under 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. Part 814.39. AstroSeal was not mentioned in any post approval periodic report under 21 C.F.R. Part 814.39(b).

92. Within six months from the time that Advanced Bionics started using AstroSeal as a feed-thru supplier, Advanced Bionics became aware of excess moisture in HiRes 90k implants implanted in the human body after such implants were returned to Advanced Bionics after being removed from patients' bodies either for medical reasons (such as implant rejection, infection, or other medical complications) or because of device failure.

93. This awareness occurred, in part, because the FDA required that Advanced Bionics perform specific testing, including hermeticity tests, on returned devices to understand the reason for device failure and to improve device reliability.

94. For those still functioning devices removed for medical reasons that showed elevated moisture levels, Advanced Bionics did not report to the FDA that the moisture exceeded the FDA limit. Nor did Advanced Bionics do any further analysis on these devices to determine where the moisture was coming from, despite Advanced Bionics' knowledge that moisture could be expected to damage the sophisticated internal electronic circuitry of its HiRes 90K devices. Advanced Bionics amended Failure Analysis Reports to remove language that devices with high moisture failed a hermeticity test.

95. Advanced Bionics still did not file a 180-Day PMA Supplement or a 30-Day Notice informing the FDA of its use of AstroSeal as a feed-thru assembly supplier. Nor did Advanced Bionics inform the FDA of its use of AstroSeal as a feedthru assembly supplier in any post-approval periodic report filed under 21 C.F.R. Part 814.39(b).

VI. Device Reporting.

96. Pursuant to federal regulations, manufacturers must report adverse events associated with a medical device to the FDA within 30 days after the manufacturer becomes aware that a device may have caused or contributed to serious injury, or that a device has malfunctioned and would be likely to cause or contribute to serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. 21 C.F.R. Part 803.50.

97. Pursuant to federal regulations, Advanced Bionics must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to the FDA as a removal or correction of the device. 21 C.F.R. Part 803.52.

98. Pursuant to federal regulations, manufacturers must report to the FDA within five (5) business days after becoming aware that an MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. 21 C.F.R. Part 803.53. An MDR reportable event is, among other things, an event that makes a manufacturer aware that a device marketed by the manufacturer has malfunctioned or may have caused or contributed to a death or serious injury. 21 C.F.R. Part 803.3.

99. Similarly, device manufacturers must report promptly to the FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of federal law caused by the device that may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. 21 C.F.R. Part 806.10.

100. Pursuant to its approved PMA, Advanced Bionics must submit an "Adverse Reaction Report" or "Device Defect Report" within 10 days after Advanced Bionic receives or has knowledge of information concerning any "adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device" and (a) has not been addressed by the device's labeling or (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

101. Advanced Bionics must submit an "Adverse Reaction Report" or "Device Defect Report" pursuant to 21 C.F.R. Part 814.82(a)(9) within 10 days after Advanced Bionic receives or has knowledge of information concerning any "adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device" and (a) has not been addressed by the device's labeling or (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

102. Advanced Bionics' head of Quality Assurance, Keith McLain, concluded that Advanced Bionics was under reporting HiRes 90K cochlear implant adverse events by 30 to 40%.

103. Advanced Bionics' failure to meet the above-referenced federal requirements applicable to medical devices and Advanced Bionics' other acts and omissions as described herein directly and proximately caused the subject device to be in violation of federal law, adulterated, unfit for sale, defective and unreasonably dangerous and the proximate and legal cause of harm to Plaintiffs.

104. Plaintiffs' state law claims against Advanced Bionics are premised, *inter alia,* on Advanced Bionics' violation of federal regulations, and are parallel state law requirements that do not conflict with and are not in addition to or different from federal requirements.

105. AstroSeal, as a manufacturer of components or parts of finished devices, was not subject to federal CGMP requirements set forth in the quality system regulation, 21 C.F.R. Part 820.

VII. The FDA required that the ICS be hermetically sealed and free of moisture.

106. Advanced Bionics' federally approved manufacturing specification required that the Device be "hermetically sealed" to prevent water intrusion.

107. Advanced Bionics federally approved manufacturing specification required that the Device have a leak rate of less than 1 x 10^{-9} cc-atm/s of helium.

108. Advanced Bionics' federally approved manufacturing specification required that the Device be 100% tested at the time of manufacture for hermeticity.

109. The expected functional life span of the Device was at least 10 years.

110. Advanced Bionics' federally approved manufacturing specification required that the Device be sealed with an inert gas mixture, 25% helium and 75% argon.

111. Advanced Bionics admitted in the PMA that the Device was designed to last for a lifetime.

112. Advanced Bionics expressly warranted the HiRes90k Device for 10 years.

113. To have any reasonable chance of operating over the anticipated 10-year life span, the Device must remain hermetically sealed and free of excessive moisture.

114. Advanced Bionics was required to comply with the CGMP, 21 C.F.R. Part 820.

115. The CGMP required that Advanced Bionics sufficiently evaluate and select AstroSeal as a supplier of feed-thru assemblies on the basis of its ability to meet specified Device requirements, as required by 21 C.F.R. Part 820.50(a).

116. The CGMP required that Advanced Bionics adequately validate Devices containing the AstroSeal feed-thru assemblies by testing production lots under actual or simulated use conditions, as required by 21 C.F.R. Part 820.30(g).

117. Advanced Bionics is and was required to qualify all critical components at the component level of a cochlear implant prior to marketing the cochlear implant to the public.

118. Advanced Bionics is and was required to qualify the HiRes 90k device at the device level using all critical components prior to marketing the cochlear implant to the public.

119. Advanced Bionics is and was required to test the HiRes 90k device in an environment that mimics the environment in which the device is to be implanted, i.e. the human body prior to marketing the cochlear implant to the public.

120. Advanced Bionics is and was required to conduct simulated life testing (which per the admission of the Director of Quality is another term for "simulated use tested") of the HiRes 90k prior to marketing the cochlear implant to the public.

121. The helium leak test does not mimic the human body.

122. Keith McLain, as Head of Quality at Advanced Bionics, testified that the helium leak test does not mimic the human body.

123. Advanced Bionics is and was required to validate the HiRes 90k using all critical components prior to marketing the cochlear implant to the public.

124. Advanced Bionics is responsible for qualification of a medical device and its components, not the FDA.

125. Advanced Bionics is responsible for validation of a medical device, not the FDA.

126. Advanced Bionics is responsible for supplier quality and audits, not the FDA.

127. Advanced Bionics is responsible for performing failure analysis testing on returned (explanted) devices, not the FDA.

128. Advanced Bionics is responsible for tracking and trending reasons for device failure, not the FDA.

129. Advanced Bionics is responsible for determining the root cause of device failure, not the FDA.

130. Patient safety is paramount to profit at a medical device company.

131. It is reckless for a medical device company to place profits over patient safety.

VIII. Advanced Bionics has known that the Device leaks since 2004.

132. In approximately July of 2003, Advanced Bionics commercially released the HiResolution cochlear implant in the United States.

133. Prior to July 2003, Advanced Bionics did not perform "actual or simulated use" testing on the HiRes90k, which Keith McLain, as Head of Quality, described as a "total deficiency in implant life cycle testing."

134. Prior to July 2003, Advanced Bionics did not perform the same qualification tests on the AstroSeal feedthru that were performed on the PA&E feedthru. In fact, Advanced Bionics did not run any test on AstroSeal feedthrus for qualification that were performed on PA&E feedthrus.

135. Prior to July 2003, Advanced Bionics did not test the HiRes90k containing an AstroSeal feedthru under actual or simulated use conditions.

136. Prior to July 2003, Advanced Bionics did not run an immersion test by attempting to force liquid water into an AstroSeal feedthru under actual or simulated use conditions.

137. Prior to July 2003, Advanced Bionics had a total deficiency in implant life testing.

138. Prior to July 2003, Advanced Bionics submitted no document to the FDA concerning the HiRes90k that mentioned AstroSeal as a component supplier.

139. Prior to July 2003, Advanced Bionics was warned by its design engineer that the HiRes 90K cochlear implant was in danger of leaking.

140. Advanced Bionics did not disclose by any means to any person that its device might leak.

141. Per Kay Adair, former Head of Regulatory Affairs to Advanced Bionics, the failure to notify the FDA of the use of AstroSeal was a "mistake."

142. Advanced Bionics nevertheless began manufacturing and marketing for sale in July 2003 to the general public, doctors and hospitals the HiRes90k cochlear implant.

143. Advanced Bionics received returned HiRes 90k implants including through September 2004.

144. Implants were removed and returned for medical reasons (for example, infection or other medical complications) or because of device failure.

145. Advanced Bionics performed hermeticity and moisture content testing on returned implants.

146. Advanced Bionics' reasons for testing returned implants included to understand the reason for device failure, to improve device reliability, and to comply with the CGMP and other applicable federal regulations applicable to medical devices.

147. On February 12, 2004, Advanced Bionics performed an RGA on an explanted device. The RGA showed that the device had moisture in excess of 0.500%.

148. On April 14, 2004, Advanced Bionics performed an RGA on an explanted device. The RGA showed that the Device had moisture in excess of 0.500%.

149. Advanced Bionics opened an investigation to understand the reason(s) for excessive moisture inside the device.

150. In June 2004, Advanced Bionics employee Josh Polack visited Pernicka Corporation.

151. During the June 2004 Pernicka visit, or shortly thereafter, Advanced Bionics learned of at least two explanted HiRes90k devices with RGA moisture/vapor percentage greater than five percent (5%).

152. By June 25, 2004, a total of fourteen (14) devices were tested, eight (8) of which (57%>) contained moisture in excess of 0.500%> In one instance the moisture/vapor content in the device was *30%.*

153. Advanced Bionics knew by at least June 25, 2004 that its devices contained moisture above specifications at an excessive and unacceptable rate and that patients were, as a result, experiencing device failure at an excessive rate and suffering hearing loss and surgery to remove the failed devices.

154. By July 2004, Advanced Bionics performed testing on its auditory manufacturing bake out ovens, and said testing confirmed said ovens were functional and effective.

155. A device will "never function" if it leaves the manufacturing facility with "sealed in" moisture of twenty percent (20%) or more.

156. In 2004, that there was a known moisture problem at Advanced Bionics involving the HiRes90k as evidenced by the following:

a. On or about August 10, 2004, Advanced Bionics was notified that the FDA would perform a for-cause inspection of its manufacturing facility.

b. In August/September 2004, former majority shareholder Al Mann ordered quality assurance employees to stop testing returned devices to keep the number of moisture failures low while the FDA was on site.

c. Keith McLain, head of Quality Assurance, at Advanced Bionics, found Mann's order to stop testing "outrageous" but complied with the order.

d. In October 2004, a former manufacturing employee named Phil Segel wrote in an email that it was known Advanced Bionics cochlear implants were leaking at the feedthru.

e. The same month, one of the designers to the HiRes90k wrote that the investigation into moisture leaking was being handled "poorly." The same person commented that he had tried to convey his feelings before but had run into an "impenetrable wall of resistance" at the company management level.

f. At the same time, other employees (including Nancy Brehm) were emailing about moisture failures in the HiRes90k as a result of leaking.

g. In December 2004, an engineer (Josh Polack) charged with investigating moisture failures in the HiRes90k wrote a memo to the file advising that data pointed to cochlear implants leaking at the feedthru.

h. Kay Adair, the former head of Regulatory Affairs at Advanced Bionics, ordered that the HiRes90k leaking be discussed "in person" and not in writing.

i. This was a known tactic at Advanced Bionics, as former Head of Quality Keith McLain discussed in 2006 the need to start "minimizing the paper trail."

j. Advanced Bionics did not reveal to doctors, audiologists, patients or potential recipients of HiRes90k devices that there was known leaking at the feedthru in October, November or December 2004. Advanced Bionics did not include this known hazard on the device label inside the package. In fact, Defendants' field staff (the employees who have direct contact with implanting physicians) were instructed on or about September 24, 2004 to tell the physicians that none of the explanted devices had experienced hermetic failures, but rather the moisture was left over from the manufacturing process. Advanced Bionics knowingly misrepresented to clinicians and patients that an internal moisture

level of below 5% was harmless when in fact its specification for maximum moisture was 0.5%.

k. Plaintiffs were not told there was known leaking in the HiRes90k device, as reported in October through December 2004 by Advanced Bionics employees.

l. Had Advanced Bionics warned Plaintiffs (or Plaintiff's physician) that Advanced Bionics cochlear implants were leaking, Plaintiffs would not have chosen the HiRes90k.

m. Advanced Bionics knew that patients would not choose its products if it revealed there was a problem with devices leaking, so the company intentionally concealed this knowledge from physicians and patients/potential patients like the Plaintiffs.

n. The actions of Advanced Bionics, as asserted below, were malicious and in flagrant disregard for the safety of persons who might be harmed by the HiRes 90k device justifying an award of punitive damages.

IX. Advanced Bionics Fails 2004 FDA Inspection.

157. On August 10, 2004, the FDA contacted Advanced Bionics to announce they would be initiating an inspection on August 25, 2004.

158. The inspection was in regards to device reliability concerns, especially hermeticity.

159. Loss of hermeticity in a cochlear implant causes harm to cochlear implant recipients.

160. No one from Advanced Bionics notified the Plaintiffs or Plaintiff's medical providers that an inspection had taken place because of device reliability concerns with the HiRes 90k in August / September 2004.

161. No one from Advanced Bionics notified the Plaintiffs or Plaintiff's medical providers that the FDA had "device reliability concerns, especially hermeticity" with Advanced Bionics' cochlear implants before Plaintiff received the Device.

162. Because of its on-going concern about the hermeticity failures, the FDA once again conducted an on-site inspection of Advanced Bionics' Sylmar, California facility on or about August 25 to September 15, 2004.

163. At this time, the FDA determined that an excessive moisture problem existed with the HiRes 90K.

164. Advanced Bionics no longer manufactured the earlier Clarion models at the time of the August-September 2004 inspection.

165. As of August 25, 2004, the FDA still did not know that Advanced Bionics was using AstroSeal as a supplier of the feedthru assembly on the HiRes90k.

166. On September 15, 2004, the FDA issued a Form FDA-483 identifying serious non-conformities and weaknesses in Advanced Bionics' quality system that required improvement.

167. The FDA identified twenty-three (23) observations of federal regulations that an inspector deemed the company was not in compliance with via the Form FDA-483.

168. The FDA Form 483 specifically states that the cause of moisture in HiRes90k units has not been determined.

169. It was the responsibility of Advanced Bionics, not the FDA, to determine the cause of moisture in HiRes90k units and fix the problem.

X. Advanced Bionics issued its first Device recall in September of 2004.

170. On September 27, 2004, as a result of the FDA inspection, Advanced Bionics initiated a Class II Recall of all of its un-implanted CLARION and HiResolution Devices, Recall Number Z-0046-05, due to the "potential presence of moisture in the internal circuitry, which can cause the device to stop functioning."

171. The FDA forced Advanced Bionics to enact the September 27, 2004 recall. The fact that the recall was "forced" and not voluntary has been admitted in deposition by the former

CEO, an Earn Out Shareholder report dated March 2006, and in an internal document entitled Auditory Talking Points dated September 24, 2004.

172. On September 29, 2004, Advanced Bionics sent a letter to HiRes 90K, Clarion 1.2, and Clarion II implant users explaining that moisture had been found on the internal circuitry of removed implants and that their implants "could stop working prematurely" if their implant was affected by this moisture problem. In its letter Advanced Bionics stated that it was recalling unimplanted products for testing. Advanced Bionics further acknowledged that sudden sensations of pain or discomfort, sudden loud noises or popping sounds, intermittent or complete loss of sound, or in children, an unwillingness to wear the external processor, were signs that a HiRes 90K might be failing. In the letter Advanced Bionics claimed that its clinics had "a simple and quick way to test whether [an implant] is fully functional."

173. The following facts are related to the September 2004 recall:

a. Advanced Bionics suspended shipment of new devices until November 8, 2004.

b. Advanced Bionics did not send out for testing the devices received back from the field following the September 2004 recall. In other words, Advanced Bionics had hundreds of devices that could have been tested to see how many had moisture inside, and Advanced Bionics did no testing.

c. In fact, Advanced Bionics re-shipped devices that were manufactured before the first recall back out into the field for implantation into children. For example, one child who currently resides in Delaware received in January 2005 a device that was manufactured in September 2004. Also, a child who resides in Colombia, South America received in November 2004 a device that was manufactured in September 2004.

d. Of course had Advanced Bionics sent out for RGA testing all devices received from the field, those devices would have contained all low-moisture levels, and Advanced Bionics did not send these devices for testing because it would have showed their devices were leaking (and did not contain sealed in moisture).

e. Advanced Bionics did not stop manufacturing devices while the HiRes90K was recalled in September 2004.

f. The assembly line kept running at full speed during the September 2004 recall, to allow Advanced Bionics to stockpile units to ship once the recall period was over.

g. Advanced Bionics manufactured 293 devices from the period of time between the announcement of the first recall in September 2004 and starting shipping in November 2004.

h. Devices manufactured during the recall time period contained the defective vendor B feedthru; were implanted into people's heads; and later had to be explanted because the defective devices failed and/or malfunctioned.

i. HiRes90k devices take six to eight weeks on average to build, per the admission of Cedric Navarro.

i. Some HiRes90k devices eventually implanted into the heads of patients were manufactured, in part, (1) before the September 2004 recall, (2) during the September 2004 recall and (3) after the September 2004 recall.

j. Manufacturing of defective devices continued during the "recall" period because majority owner and Co-CEO Al Mann considered the FDA quality deficiency observations to be without merit and further because Mann considered the Advanced Bionics HiRes 90K cochlear implant to be without defect.

k. Furthermore, and as discussed in more detail below, if Advanced Bionics would have stopped manufacturing devices during the first recall, the company Earn Out shareholders, e.g. the upper management and employees, would have lost out on lucrative bonuses paid by then parent company Boston Scientific.

174. From September 27, 2004 until November 1, 2004 at the latest, Advanced Bionics investigated the purported reasons for HiRes90k devices being returned with high moisture.

175. The investigation was suspect:

a. As part of this process, Advanced Bionics investigated the bake-out ovens used in the manufacturing and made enhancements to the bake-out process.

b. Former employee Phil Segel, however, testified in a deposition that the bake out ovens had been tested to be functional in 2003, more than a year before the recall.

c. Advanced Bionics never tested whether its devices were leaking because to do so would cause Advanced Bionics to totally stop

shipping the HiRes90k device, and start the qualification process all over again.

176. In all, the September 2004 recall was merely a fraud on consumers, including the Plaintiff.

XI. The FDA found that Advanced Bionics' Devices were adulterated.

177. On February 1, 2005, the FDA issued Advanced Bionics a "Warning Letter" identifying eighteen (18) "significant deviations" from federal regulations in the "manufacturing, packaging, storage or installation" of medical Devices.

178. The FDA reported to Advanced Bionics that its inspection "disclosed that your [cochlear implant] devices are adulterated" within the meaning of Section 501(h) of the Federal Food, Drug and Cosmetic Act.

179. The FDA reported that Advanced Bionics was in violation of the CGMP regulations for medical devices set forth in the quality system regulation, specified in 21 C.F.R. Part 820.

180. In specific, the FDA detailed eighteen (18) deviations where the "methods used in, or the facilities or controls used for manufacturing, packaging, storage or installation" were "not in conformance with the Cun-ent Good Manufacturing Practice (CGMP) requirements for medical devices as set forth in specific federal regulations." The noted deviations in the Warning Letter included, but were not limited to, Advanced Bionics':

a. failure to conduct management reviews with sufficient frequency as required by 21 C.F.R. Part 820.20(c), even though Advanced Bionics was aware that a significant manufacturing deficiency, moisture in HiRes 90K devices, was occurring;

b. failure to establish procedures for conducting quality audits and failure to conduct such audits to assure that Advanced Bionics' quality system was in compliance with the established quality system requirements and to determine the effectiveness of the quality system as required by 21 C.F.R. Part 820.22;

c. failure to establish procedures for identifying training needs and to ensure that all personnel were adequately trained to perform their assigned responsibilities, as required by 21 C.F.R. Part 820.25(b),

including that there was "inadequate knowledge regarding how [RGA] results could be used to determine if a device was hermetically sealed with water within the device at the time of manufacture or if the water entered the device as a result of a loss of hermeticity";

d. failure to document the 0.500% (5,000 ppm) "water content limit for the [HiRes 90K]" in a design input document as required in 21 C.F.R. Part 820.30(c);

e. failure of design verification to confirm that design output meets design input requirements as required by 21 C.F.R. Part 820.30(f), including that "there was no design verification and validation for the HiRes 90K product to meet the water content limit of less than 0.500% (5,000 ppm)";

f. failure to perform a risk analysis, as required by 21 C.F.R. Part 820.30(g), in that risk analysis was performed using single point fault conditions, which did not consider that loss of hermeticity or moisture trapped in a sealed device could result in multi-point failure in the implant;

g. failure to adequately validate manufacturing processes as required by 21 C.F.R. Part 820.75(a);

h. failure to establish and maintain a procedure for monitoring and control of process parameters for validated processes or to revalidate when changes or process deviations occur as required by 21 C.F.R. Part 820.75(b) & (c), especially related to the vacuum bake procedures;

i. failure to develop, conduct, control or monitor product processes to ensure that a device conforms to its specifications, as required by 21 C.F.R. Part 820.70(a), including a lack of monitoring and recording of vacuum pressure to ensure that vacuum level was maintained during the vacuum baking process to remove water/moisture prior to sealing;

i. failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch met acceptance criteria as required by 21 C.F.R. Part 820.80(d) including that Advanced Bionics' finished devices were not screened for gross leakage and there was no verification that the proper vacuum pressure was used;

j. failure to investigate the causes of nonconformities to product, process, and quality, or to identify the actions needed to correct and prevent such reoccurrences as required under 21 C.F.R. Part 820.100(a) (2) & (3) including the failure to adequately analyze explants removed for medical reasons to determine whether any electronic circuit board damage might have resulted from moisture damage that had not yet caused device failure;

k. failure to ensure that information related to quality problems or nonconforming product was disseminated to those directly responsible for ensuring quality of product or of such problems as required by 21 C.F.R. Part 820.100(a)(6), including that all available information related to device failures was not forwarded to the FDA as updates to the MDR; and

l. failure to comply with the PMA, including that the FDA was not informed that moisture was found in six out of eleven (55%) explanted devices that were still functioning and removed for medical reasons such as infection.

181. The FDA reported to Advanced Bionics that "[u]ntil you have adequately demonstrated that you have corrected the violations . . . we continue to believe that the violations still pose a significant risk to public health."

182. The FDA directed that Advanced Bionics take "prompt action to correct these deviations" and that failure to do so may result in "seizure, injunction, and/or civil penalties."

183. The Letter also stated that "the specific violations noted in this letter . . . may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system" and that Advanced Bionics (not the FDA) was "responsible for determining and investigating the causes of the violations identified by the FDA."

184. In February 2005, the same month that the FDA issued its Warning Letter, auditory division president James (Jim) Miller wrote that HiRes 90k device failures "continue to occur at an alarming rate." See Email of James Miller (Ex. B). However, that information was concealed from clinicians and patients.

185. In response to the Warning Letter, Advanced Bionics sent no Medical Device Correction Letter to doctors or other clinicians as required by industry standards.

186. Failures of HiRes90k devices using an AstroSeal feedthru continued throughout 2005.

187. Advanced Bionics still continued using AstroSeal as a feedthru supplier even though Advanced Bionics knew that no qualification test plan had been carried out to ensure that AstroSeal implants were in compliance with its intended use in the human body.

188. On or before March 2005, Advanced Bionics was aware that post-2004 recall HiRes 90K devices were failing and had high levels of moisture, yet it did not recall the current model HiRes 90K or inform the FDA of its use of AstroSeal as a feedthru supplier, even though Advanced Bionics was aware of serious quality issues with AstroSeal feedthrus.

XII. Internal audits confirmed serious ongoing problems at Advanced Bionics.

189. Internal audits found serious ongoing quality problems at Advanced Bionics in 2004, 2005 and January-February 2006.

190. Shortly after the FDA Warning Letter, BSC, the corporate parent of Advanced Bionics at the time with a principal place of business in Natick, Massachusetts, performed an internal investigation and audit of quality control at Advanced Bionics.

191. The audit discovered seven (7) major non-conformities and many uncorrected issues remaining from the 2004 Form 483 observations issued by the FDA.

192. In February of 2006, BSC contracted with an independent quality auditor, Quality Hub, to do an onsite audit of Advanced Bionics to verify the adequacy and completeness of Advanced Bionics corrective actions related to the 2004 Form 483 and the 2005 Warning Letter observations.

193. Specifically, Quality Hub arrived at the Advanced Bionics facility on February 21, 2006. The same day of Quality Hub's arrival, Advanced Bionics instituted belated corrective action to address the long-standing problem of leakage in the HiRes 90K cochlear implant, such as the one in the Plaintiff's head.

194. The Quality Hub audit uncovered numerous deficiencies at Advanced Bionics. Advanced Bionics has admitted this fact.

195. Advanced Bionics failed to timely correct deviations noted by the FDA and by its internal auditors.

196. At all relevant times, Advanced Bionics remained out of compliance with federal requirements.

197. Advanced Bionics knew that device failures continued to occur in 2005 and 2006 at an alarming rate as a result of moisture insid e the devices.

198. Advanced Bionics knew that the manufacturing process and quality changes it had implemented in 2004 had not solved its moisture problem. Facts supporting the allegation include:

a. In October 2004, Phil Segel admitted devices were leaking at the feed-thru.

b. By November 1, 2004, all "fixes" to the bake-out oven were complete.

c. In December 2004, Josh Polack wrote that the evidence pointed to HiRes 90K devices leaking at the feed-thru.

d. Advanced Bionics did not pull its devices off the market in October, November or December 2004 despite corporate employees admitting that devices were leaking.

e. In February 2005, the president of the auditory division admitted devices were continuing to fail at an alarming rate.

f. Advanced Bionics still did not stop shipping the device.

g. In March 2005, Advanced Bionics received a HiRes 90K manufactured after the "fix" to the bake-out oven which was found to contain high moisture.

h. Advanced Bionics continued to ship its devices after it received this device.

i. Advanced Bionics received another "post-fix" HiRes 90K with high moisture in July 2005.

j. Advanced Bionics employee Alex Guttierez admitted that two out of specification devices sets a trend.

k. Advanced Bionics opened CAPA 210 (that related to yet another problem with the HiRes90k) because two devices were returned out of specification.

l. In 2010, Advanced Bionics recalled the HiRes90k for the third time in a decade after two devices were returned out of specifications.

m. Advanced Bionics did not recall, stop shipment or open a CAPA for high moisture in July 2005.

n. Advanced Bionics continued to receive devices with high moisture from August 2005 to January 2006.

o. Advanced Bionics did not recall, stop shipment or open a CAPA for high moisture from August 2005 to January 2006.

p. In October 2005, Exponent advised Advanced Bionics that the odds it was manufacturing devices with sealed-in moisture was 1 in 10,000.

q. The Exponent report proved it was scientifically and statistically impossible to have sealed moisture in the devices manufactured after 11/1/04 that were returned with high moisture.

r. Advanced Bionics still did not start taking corrective action until February 21, 2006.

s. The recall did not occur until March 2006.

t. Despite there being a recall in March 2006, Advanced Bionics waited approximately 90 days to reveal the recall to those patients that received unapproved, untested HiRes90k devices containing the vendor B feedthru.

198. Advanced Bionics maliciously and with flagrant disregard of the safety of persons who might be harmed by its cochlear implants continued to market and sell cochlear implants in 2003, 2004, 2005 and early 2006 despite knowing that the devices had a moisture problem, having repeatedly been cited by the FDA for violations of federal regulations, including the CGMP, and yet Advanced Bionics failed (1) to properly test, qualify and validate the HiRes 90k device using an AstroSeal feed-thru, (2) to disclose the use of AstroSeal to the FDA and (3) to identify the root cause of the moisture problem and solve it in time to prevent the Plaintiff from receiving a leaky Device that failed because of water intrusion.

XIII. Advanced Bionic recalls again in March 2006.

199. On March 8, 2006, Advanced Bionics initiated two Class II recalls of all unimplanted HiRes90k cochlear implants containing feed-thru assemblies manufactured by AstroSeal, Recall Number Z-0759-06 for Model number CI-1400-2H and Recall Number Z-0758-06 for Model Number CI-1400-01.

200. Advanced Bionics initiated the recall because it belatedly acknowledged that HiRes90k devices containing the AstroSeal feed-thru were causing premature device failure and temporary and permanent hearing loss, pain, and suffering to patients and requiring surgery to remove and replace defective implants. Advanced Bionics also initiated the recall because the devices containing the AstroSeal feed-thru were out of compliance with federal requirements and the CGMP.

201. On March 15, 2006, Advanced Bionics admitted to the FDA that it had not previously disclosed the use of AstroSeal as a feedthru supplier in the HiRes90k.

202. Devices containing the AstroSeal feed-thru were adulterated, misbranded, and non-compliant with the company's own standards and FDA-approved specifications.

203. Advanced Bionics finally admitted that moisture was not entering its implants during its manufacturing process, but instead, that moisture was leaking into the device through a defective feed-thru assembly manufactured by AstroSeal after the devices had been shipped and implanted in patients.

204. Advanced Bionics finally admitted that the feed-thru manufactured by AstroSeal failed to reliably maintain a hermetic seal resulting in moisture content inside the devices above the company's 0.500% specification.

205. The defective AstroSeal feed-thru, according to Advanced Bionics, came to light after the product reached market and was not included or referenced in any manner in connection with the company's filings with the FDA.

206. Advanced Bionics failed to include any warning or labeling to the effect that its devices were not hermetically sealed and could leak after implementation in the human head in violation of 21 C.F.R. 801.109 and the law of Kentucky, and failed to update its label once it became aware of hazards, contraindications, side effects, and/or necessary precautions, as permitted by 21 C.F.R. 814.39(d) and required by federal law and the law of Kentucky.

207. Instead of the inert argon and helium gas that was supposed to be present inside the devices, defective AstroSeal feed-thrus contained moisture vapor.

208. The AstroSeal feed-thru, according to Advanced Bionics, "was not designed and built to effectively keep moisture out."

209. The AstroSeal feed-thru, according to Advanced Bionics, "did not meet our standards."

210. According to Advanced Bionics' Summer 2007 Auditory Reliability Report, 79.8% of Devices containing the Astro-Seal feed-thru were functional after 3 years. This figure has continued to fall. As of today, almost 40% of HiRes 90K devices with AstroSeal feed-thrus have failed.

211. For a Device warranted to last 10 years, failure of 20% of the Devices containing the AstroSeal feed-thru after 3 years as a result of moisture intrusion is an outrageous and catastrophic failure rate not approved by FDA and unacceptable by any standard of reliability, including Advanced Bionics' own standard.

212. By contrast, according to Advanced Bionics, its devices manufactured with a PA&E. feed-thru have a failure rate of 1.5% after 3 years.

213. Advanced Bionics had information on the problem with the AstroSeal feed-thru assembly prior to March of 2006, but failed to timely notify the FDA and the medical community and patients and failed to take appropriate action to prevent harm to patients receiving the device.

214. There was at Advanced Bionics a program known as the Earn Out Program, a formula by which shares of stock in Advanced Bionics were purchased by Boston Scientific:

a. In the spring of 2004, Al Mann, on behalf of Advanced Bionics shareholders, began to market Advanced Bionics for sale to a third party.

b. In June 2004, Boston Scientific and Advanced Bionics reached a deal whereby Boston Scientific would purchase Advanced Bionics stock.

c. Shareholders were offered two means for payment of their stock: (1) a cash payout or (2) future payments plus a smaller cash payoff, with the future payments benchmarked on several factors including the number of cochlear implants shipped (the "Earn Out").

d. There was no quality benchmark to the Earn Out program, so if a cochlear implant was returned as defective, there would not be a credit against a device that previously was counted toward the Earn Out benchmarks.

e. Employees over the course of the Earn Out were paid millions of dollars for the sale of defective Advanced Bionics HiRes90k units.

f. By the admission of the Defendant Advanced Bionics, at the very least $64 million dollars in bonuses were paid on the sale of cochlear implants, i.e. the device that was deemed adulterated by the FDA in February 2005 and in 2007.

g. It is believed that payments were much higher than $64 million and that indeed hundreds of millions of dollars were paid in bonuses to Advanced Bionics shareholders.

h. Following the March 2006 recall, Advanced Bionics shareholders were not asked to refund earn out bonus payments and pay those sums of money to the many injured by the defective HiRes90k.

i. In fact, Boston Scientific believes that Advanced Bionics employees delayed recalling the HiRes90k until March 2006 so the shareholders could receive their bonus payments in February 2006 in the Earn Out program.

215. The Devices containing AstroSeal feed-thru assemblies were defective, negligently designed and manufactured, unreasonably dangerous, and not in compliance with any applicable standard or regulation, including FDA-approved device manufacturing specifications and CGMP regulations promulgated by the FDA.

XIV. FDA's February 2007 Inspection.

216. The FDA conducted an additional on-site inspection on February 20-27, 2007, which focused on Advanced Bionics' activities related to the March 8, 2006 recall. During the inspection, the FDA investigators discussed with Advanced Bionics three separate violations of

the required PMA supplementation for changes to the HiRes 90K, including the failure to seek approval for the changes to the feedthru assemblies supplied by AstroSeal and failure to test HiRes90k units under actual or simulated use conditions before sale to the public.

217. FDA learned that Advanced Bionics had not performed all of the FDA required testing before using AstroSeal as a feedthru vendor even though Advanced Bionics had conducted some of these tests for the PA&E feed-thru.

218. FDA found that Advanced Bionics had qualified AstroSeal as a supplier for the feedthru component based on helium leak testing, but did not conduct (1) hydrostatic pressure testing, (2) corrosion (soak) testing, or (3) simulated use life testing in an environment that simulated the human body, all of which involved immersion of the devices in saline solution similar to that of the human body, and did not conduct functional electrical testing to assess performance under actual stimulation conditions.

219. The helium leak test used by Advanced Bionics was a modified version of an acceptable helium leak test. Further, the helium leak test does not simulate the human body.

XV. FDA files an enforcement action against Advanced Bionics for violating federal law.

220. As the result of the 2007 inspection, the FDA filed a complaint in November 2007 against Advanced Bionics and its President and Co-CEO Jeffrey H. Greiner ("CEO Greiner") seeking administrative penalties related to Advanced Bionics' violation of the FDCA and its implanting regulations. The FDA amended its Complaint on March 17, 2008. See Amended FDA Complaint (Ex. C).

221. The amended complaint sought a $2.2 million penalty against Advanced Bionics for violating federal law, including the CGMP standards and failure to notify the FDA of a change in an outside supplier of the feed-thru component to Astro-Seal, thereby exposing recipients of the device to unnecessary health risks.

222. Specifically as to the FDA civil monetary penalty action:

a. The FDA announced that the device poses a "public health risk due to excessive moisture, exposing patients to the risk of device failure, possible surgery, and the potential for additional hearing loss."

b. According to the FDA, Advanced Bionics CGMP violations include "the failure to sufficiently evaluate and select a new vendor as the supplier of a critical Device component and the failure to adequately validate the continued safety and effectiveness of the hearing aid by testing lots under actual or simulated use when the unapproved vendor's component was used."

c. According to the FDA, "Advanced Bionics shipped hearing aids in violation of the law between January 2005 and July 2006."

d. The FDA found that the design criteria and specifications of the AstroSeal feedthru components were materially different than the design criteria and specifications submitted to the FDA, thus constituting a violation of federal law.

e. The FDA further found that qualifying AstroSeal only on the basis of helium leak testing and not the hydrostatic pressure testing, corrosion soak testing, or functional soak testing to access performance under actual stimulation parameters, constituted a violation of federal law.

f. The FDA found that HiRes 90K devices containing Astro-Seal feedthrus were adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B) in that the HiRes 90k implants with an AstroSeal feed-thru did not have the required premarket approval for Class III devices "because changes were made that affected the safety and effectiveness" of the device when AstroSeal was used as a feedthru supplier, and yet Advanced Bionics did not file either a 180-Day PMA Supplement or 30-Day Notice under 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. Part 814.39.

g. The FDA further alleged that Advanced Bionics had violated the CGMP requirements in that the methods used in, and the facilities and controls used for, manufacturing, packaging, storage, and installation were not in conformity with CGMP requirements for Class III medical devices as set forth in the Quality System Regulation at 21 C.F.R. Part 820, including, but not limited to, Advanced Bionics:

i. failed to sufficiently evaluate and select AstroSeal as a feedthru supplier on the basis of ability to meet specified device requirements, as required 21 C.F.R. Part 820.50a(a);

ii. failed to adequate validate devices containing AstroSeal feedthrus by testing production lots under actual or simulated use conditions, as required by 21 C.F.R. Part 820.30.

h. The FDA stated that HiRes 90K devices containing the AstroSeal feedthrus constituted a public health risk because the excessive moisture exposed patients in whom the device was implanted to the risk of device failure, and the associated risks of surgical intervention, including anesthesia, meningitis, and permanent neurological damage.

i. The FDA also found that excess moisture also could lead to direct current leakage, which could result in permanent injury to the auditory nerve and loss of hearing.

223. Shortly after a second amended Complaint was filed by the FDA on July 7, 2008, the FDA and the Advanced Bionics settled the Administrative Action with Advanced Bionics agreeing to pay a $1.1 million fine, which is the maximum fine allowed in an administrative action. CEO Jeff Greiner agreed to pay a $75,000 fine personally.

224. Plaintiff suffers from profound bilateral sensorineural hearing loss.

225. Following review of Defendants' promotional materials, he was implanted with an Advanced Bionics HiRes90k cochlear device Model CI-1400-01, serial no. 310433, and identification no. 2007-12 on February 1, 2006 by Charles Woods, MD at University Hospital, SUNY Upstate Medical University, 750 East Adams Street, Syracuse, New York 13210.

226. Upon information and belief, Plaintiff's HiRes90k device contained an AstroSeal feedthru and/or was otherwise defective.

227. Defendants failed to warn and/or advise Plaintiffs, Plaintiff's surgeon or Plaintiff's audiologist:

a. that Plaintiff's HiRes90k Device was manufactured and marketed using AstroSeal as a feed-thru supplier without FDA approval, that Plaintiff was receiving an untested, invalidated and unqualified Device with an AstroSeal feed-thru, or that the Plaintiff was receiving an "adulterated" and experimental Device as that term is defined by FDA regulations;

b. that Al Mann, the Co-Chief Executive Officer and majority owner of Defendant Advanced Bionics, had instructed that testing of

Advanced Bionics returned devices stop in August / September 2004 until after the FDA left the facility;

c. that Plaintiff's HiRes90k device received was not tested under actual or simulated use conditions before the device was marketed in July 2003;

d. that an Advanced Bionics engineer advised before Plaintiff was implanted that there was not enough data to determine whether AstroSeal feedthrus were reliable;

e. that the HiRes90k with an AstroSeal feedthru was not subjected to the same qualification tests as the HiRes90k with a PA&E feedthru;

f. that Advanced Bionics knew at the latest by October 2004 that HiRes90k devices were leaking at the feedthru;

g. that there was a known hazard of leaking in the device as of October 2004; and

h. that there was a rash of HiRes 90K failures immediately preceding Plaintiff's implantation with a defective device of which Advanced Bionics was fully aware.

228. Plaintiff never received an optimal result with the Device.

229. Plaintiff reported ongoing communication disorders including but not limited to January 12, 2012, March 30, 2012 and October 18, 2013.

230. Plaintiff's device was confirmed as having failed, requiring replacement surgery.

231. Upon information and belief, Plaintiff's device failed as a result of water intrusion into the device through nanocracks in the oxide layer of an AstroSeal feed-thru or otherwise.

232. Plaintiff will require removal and re-implantation with another device in a surgery under general anesthesia.

233. Plaintiff has suffered and will suffer from extensive pain and suffering.

CAUSES OF ACTION

COUNT I

NEGLIGENCE

234. Plaintiffs hereby incorporate by reference all preceding paragraphs of Plaintiff's Complaint as if fully set forth herein.

235. At all relevant times, Defendants had a duty and continued to owe a duty to Plaintiffs: (a) to provide a safe and effective Device in design and manufacture, (b) to notify physicians, patients, prospective patients and the FDA of design flaws and known hazards with the Device, (c) to manufacture and test the Device properly (including by testing under actual or simulated use) in compliance with applicable industry standards, regulations and FDA-approved specifications, and (d) to notify physicians (including Plaintiff's physicians), patients and prospective patients (including Plaintiff), of the defective nature or hazardous conditions with the Device and that the Device contained an unapproved critical component, was prone to leaking, and was not tested prior to initial marketing in an environment that simulated the end use environment.

236. Defendants breached their duty of reasonable care to Plaintiffs in a number of ways, including but not limited to the following:

a. by incorporating a defect into the design of the Device;

b. by failing to manufacture the Device within the standard of care;

c. by failing to properly test, validate and quality the feed-thru and Device;

d. by deviating from the Pre Market Application by using the AstroSeal feedthru in the manufacture of the Device in violation of 21 C.F.R. part 814.39;

e. by failing to test the HiRes90k under actual or simulated use conditions prior to sale of the Device (also known as life cycle testing, as these tests are one in the same per Keith McLain) in violation of 21 C.F.R. part 820.30(g);

f. by failing to ensure that a critical component manufacturer produced a component that conformed to the specifications of Advanced Bionics and performed as Advanced Bionics intended it to do, which Advanced Bionics failed to do for the AstroSeal feedthru in that Advanced Bionics did not even perform a single qualification test on the AstroSeal feedthru that it did on the PA&E feedthru, did not audit AstroSeal, did not validate its processes using the AstroSeal feedthru did not perform system-level qualification of the HiRes90k using the AstroSeal feedthru, in violation of 21 C.F.R, 820.50 and 820.80p;

g. by failing to implement improvements to its quality system prior to the implantation of the Plaintiff in violation of 21 C.F.R. 820.20 and 21 C.F.R. 820.22, as Advanced Bionics admitted that its quality system was knowingly substandard in 2004;

h. by failing to track, trend, monitor and investigate device failures in violation of 21 C.F.R. 820.100 and 820.198, in that the Defendants did not track and trend failure modes by critical component vendor, and doing so would have revealed the defective nature of the HiRes90k with an AstroSeal feedthru;

i. by failing to adequately train its employees in quality, which the company admittedly did not do in violation of 21 C.F.R. 820.25(b);

j. by failing to validate its processes using a cochlear implant containing the AstroSeal feedthru in violation of 21 C.F.R. 820.30(f);

k. by failing to develop, conduct, control and monitor production processes, to ensure that a device conforms to its specifications, as required by 21 C.F.R. 820.70(a), in that Advanced Bionics did not adequately qualify the AstroSeal component, did not qualify the HiRes90k with an AstroSeal feedthru, did not validate its processes using a HiRes90k containing an AstroSeal feedthru and did not test the HiRes90k under actual or simulated use conditions (i.e. perform life cycle and/or accelerated life cycle testing);

l. by failing to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meet acceptance criteria, as here the device received by Plaintiff did not as the Device leaked and contained excessive moisture resulting in explanation of the Device;

m. by failing to timely open a Corrective and Preventative Action (CAPA) to address leaking in HiRes90k devices, which Advanced Bionics should have done at least as early as October 2004 and at numerous instances thereafter before Plaintiff received the Device, in violation of 21 C.F.R. 820.20(b)(2);

n. by failing to timely report to the FDA within 30 days device malfunction in violation of 21 C.F.R. 803.50; by failing to timely report to the FDA within 30 days device failures resulting in substantial harm to a patient in violation of 21 C.F.R. 803.53;

o. by failing to adequately label the device for known hazards and/or defects, which included leaking at the feedthru and alarming failure rates, in violation of 21 C.F.R. 801.109(c);

p. by failing to update the label for the device to include known hazards and/or defects, which included leaking at the feedthru and alarming failure rates, in violation of 21 C.F.R. 801.109(c) and as allowed by 21 C.F.R. 814.39(d);

q. by failing to warn Plaintiffs of the risk that the Device would not be hermetically sealed and free of excessive moisture;

r. by failing to disclose to the U.S. medical community that the AstroSeal feedthru may leak causing the Device to malfunction and prematurely fail;

s. by failing to instruct or warn the U.S. medical community that the effectiveness of the Device utilizing the AstroSeal feedthru had not been established;

t. by failing to disclose to the U.S. medical community that the AstroSeal feedthru had not been tested to ensure that the feedthru did not leak;

u. by failing to disclose to the U.S. medical community that the use of the AstroSeal feedthru in the Device had not been disclosed to or approved by the F.D.A.; and

v. by failing to disclose to the U.S. medical community that the Device utilizing the Astroseal feedthru had not undergone the safety and efficacy testing required by the F.D.A.

237. As a direct and proximate result of Defendants' wrongful conduct, including failure to comply with applicable FDA requirements and FDA-approved Device specifications, Plaintiffs have sustained and will continue to sustain severe physical injuries, hearing loss, unnecessary surgery, severe emotional distress, economic losses and other damages for which they are entitled to compensatory damages in an amount to be proven at trial.

238. These damages have been continuing in nature, causing Plaintiffs' injuries, pain and suffering, and economic loss.

COUNT II

STRICT LIABILITY

239. Plaintiffs hereby incorporate by reference all preceding paragraphs of Plaintiffs' Complaint as if fully set forth herein.

240. The Device was unreasonably and dangerously defective beyond the extent contemplated by ordinary patients with ordinary knowledge regarding the device, in one or more

a. the foreseeable risks of mechanical malfunction and failure using a device that leaks water outweighs the benefits associated with the device, particularly given that correct manufacturing

technology allows medical device manufacturers to produce devices that do not leak to an excessive degree;

b. the labeling failed to disclose to the U.S. medical community that the AstroSeal feedthru utilized in the Device could leak causing the Device to malfunction and prematurely fail;

c. the labeling failed to disclose to the U.S. medical community that the effectiveness of the Device was uncertain;

d. the labeling failed to disclose to the U.S. medical community that the AstroSeal feedthru had not been tested to ensure that the feedthru did not leak;

e. the labeling failed to disclose to the U.S. medical community that the use of the AstroSeal feedthru in the Device had not been disclosed to or approved by the F.D.A.;

f. the labeling failed to disclose to the U.S. medical community that the Device utilizing the Astroseal feedthru had not undergone the safety and efficacy testing required by the F.D.A;

g. the Device was designed and manufactured to be implanted as a cochlear device utilizing an AstroSeal feedthru, and;

h. when used as designed and directed, the AstroSeal feedthru used in the device would develop nanofractures and leak water into the device causing the device to malfunction and prematurely fail necessitating additional surgery.

241. The devices were designed and/or manufactured in a manner violative of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 *et seq.* (hereinafter "FDCA") and applicable FDA regulations. The facilities or controls used by Defendants in the manufacture, packing, storage, or installation of the devices were not in conformity with applicable regulations and FDA-approved specifications for the device or the CGMP requirements set forth in FDA's quality system regulations, 21 C.F.R. Part 820.

242. Defendants knew or should have known of the design and manufacturing defect and the risk of serious bodily injury that exceeded the benefits associated with the design of the Device.

243. Furthermore, the Device and its defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

244. The Device is inherently dangerous for its intended use due to design and/or manufacturing defect and improper functioning. Defendants are, therefore, strictly liable.

245. Defendant violated New York Consumer Protection Laws.

246. As a direct and proximate result of Defendant's wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, hearing loss, unnecessary surgery, severe emotional distress, economic losses, and other damages for which they are entitled to recover in an amount to be proven at trial.

247. Defendant is liable to Plaintiffs for all general, special, and equitable relief to which Plaintiffs are entitled by law.

248. These damages have been continuing in nature, causing Plaintiffs' injuries, pain and suffering, and economic loss.

COUNT III

NEGLIGENCE PER SE

249. Plaintiffs hereby incorporate by reference all preceding paragraphs of Plaintiffs' Complaint as if fully set forth herein.

250. Defendants have an obligation not to violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, distribution, advertising, preparing for use, warning of the risks and dangers of the Device.

251. Defendants were negligent in at least the following ways, although there are additional means by which the Defendants were negligent for violation of federal statutory and regulatory law.

252. Defendants deviated from the FDA-approved design and manufacturing specifications for the HiRes 90k by, among other things, using a feed-thru component manufactured by AstroSeal rather than a feed-thru component manufactured by PA&E, including the violations described in the 2004 and 2005 FDA Form-483s and 2007 FDA Amended Complaint.

253. Defendants failed to obtain supplemental PMA approval for use of the AstroSeal feed-thru component through a 180-Day PMA Supplement or 30-Day Notice under 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. Part 814.39, including to the violations described in the 2004 and 2005 FDA Form-483s and 2007 FDA Amended Complaint.

254. Defendants failed to comply with the conditions of approval specified in the FDA PMA approving the HiRes 90k and earlier PMAs including, without limitation, the requirement that Defendants obtain supplemental approval prior to making any change that could affect the safety and effectiveness of a device.

255. Defendants failed to comply with applicable CGMPs in the manufacture of the HiRes 90k including, but not limited to, the violations described in the 2004/2005 FDA Form 483s, 2005 FDA Warning Letter; and the 2007 FDA Amended Complaint.

256. Defendants failed to comply with applicable adverse event reporting requirements involving the HiRes 90k, including, but not limited to, the violations described in the 2005 FDA Warning Letter; and the 2007 FDA Amended Complaint.

257. Defendants failed to ensure that HiRes 90k devices contained no more than 0.500% (5,000 ppm) moisture as required by its PMA.

258. Defendants failed to sufficiently evaluate and select AstroSeal as a supplier of feed-thru assemblies on the basis of its ability to meet specified device requirements as required by the FDA CGMPs.

259. Defendants failed to adequately validate the HiRes 90k devices by testing production lots under actual or simulated use conditions.

260. The manufacture of the HiRes90k was performed in violation of the Code of Federal Regulations and the federal statutory law.

261. Defendants' acts constitute an adulteration, misbranding, or both, as defined by the Federal FDCA, 21 U.S.C. §§ 331(a) and 333(a)(2) and applicable FDA regulations, and

constitute a breach of duty subjecting Defendants to civil liability for all damages arising therefrom and from parallel state law requirements, under the theory of negligence per se.

262. Plaintiffs, as purchasers of the Defendant's Device, are within the class of persons the statutes and regulations described above are designed to protect, and Plaintiffs' injuries are the type of harm these statutes and regulations are designed to prevent.

263. As a direct and proximate result of Defendant's wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries and/or death, severe emotional distress, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial. Defendant is liable to Plaintiffs for all general, special, and equitable relief to which Plaintiffs are entitled by law.

264. These damages have been continuing in nature, causing Plaintiffs' injuries, pain and suffering, and economic loss.

COUNT IV

NEGLIGENT MISREPRESENTATION AND FRAUD

265. Plaintiffs repeat, reallege and incorporate herein by this reference all of the preceding allegations as though set forth in full.

266. Defendants knowingly and intentionally made express and implied material and false and misleading representations to Plaintiffs, Plaintiff's physicians, and to the public that the HiRes 90k devices were of merchantable quality, in compliance with federal law and regulations, not adulterated, safe for the use for which they were intended, and that Defendants' labeling, marketing and promotion fully described all known risks of the products. These misrepresentations and omissions of fact include, but are in no way limited to:

a. Advanced Bionics never disclosed to Plaintiffs or Plaintiff's physicians that it did not supplement its PMA Application to include the AstroSeal feed-thru.by deviating from the Pre Market Application by using the AstroSeal feedthru in the manufacture of the Device in violation of 21 C.F.R. part 814.39;

b. Advanced Bionics never disclosed to Plaintiffs or Plaintiff's physicians or audiologists that it did not test the HiRes 90k device

in a simulated environment in which the device was to be before commencement of marketing the device;

c. Advanced Bionics never disclosed to Plaintiffs or Plaintiff's physicians and audiologists that it had surreptitiously commenced life cycle testing in an environment which simulated the human body in 2004, and within 70 days, 50% of the test devices had failed;

d. Advanced Bionics never disclosed to Plaintiffs or Plaintiff's physicians that there was a history of device failures related to moisture with the Clarion and Clarion II Advanced Bionics cochlear implant devices; and

e. Advanced Bionics made representations via comments to Plaintiffs and/or Plaintiff's physicians through oral representations and/or written promotional and marketing materials that its products were the most technologically advanced and the safest.

267. In addition, the following was true as of the date that Plaintiff was implanted with Plaintiffs Device:

a. The HiRes90k was not tested before marketing in an environment that simulated the human body;

b. The HiRes90k was belatedly subjected to accelerated life-cycle testing and 50% of the test devices failed;

c. Advanced Bionics declared that it would not wait for all risks to be studied before selling the device that Plaintiff received;

d. The FDA had previously cited AB in a Form 483 in 2001 for failing to submit PMA applications for manufacturing processes and design changes;

e. There were more than 100 devices that failed for leaking in predecessor generation devices;

f. Of the devices leaking, AB was aware by May 2002 that devices were leaking, among other places, through the feedthru (the same component where Plaintiff's device leaked);

g. A "Hermeticity Task Team" was set up by Advanced Bionics to solve the "major problems" of leaking with AB cochlear implant

h. AB engineers admitted that there was "not enough data to determine how reliable the AstroSeal feedthrus would be" in January 2003;

i. There was a problem with the "seal fixture" in the HiRes90k using AstroSeal feedthrus in February 2003;

j. There was knowledge that the hermeticity problems AB was experiencing with PA&E devices was applicable to AstroSeal, as well, before Plaintiff was implanted; and

k. AB admitted in April 2003, before Plaintiff was implanted, that it would not know the "long term effectiveness" of the HiRes90k feedthru for "years."

268. Defendants knowingly or recklessly made material false representations to Plaintiffs and Plaintiffs' healthcare providers about the functionality of Plaintiff's HiRes 90k Devices with the intent that Plaintiffs would act and/or refrain from acting on its representations.

269. Plaintiffs and Plaintiffs' healthcare providers relied upon said representations of Defendants in the selection, purchase, and use of the HiRes 90k device, and but for the falseness of those representations, implantation would not have occurred and/or Plaintiff's defective Device would have been removed much earlier.

270. Said representations by Defendants were false and untrue, in that the HiRes 90k devices were not in compliance with federal safety regulations and laws (set forth above), were adulterated, were not safe for their intended use, nor were they of merchantable quality or functional devices as represented by Defendants. Defendants were aware that the devices had very dangerous properties and defects that could potentially cause injury and damage to the users of the HiRes 90k devices, including Plaintiff, thereby threatening the health, life, and hearing of Plaintiff.

271. At all times relevant to this action, prior to and at the time Defendants sold the devices and while they were surgically implanted, Defendants knew, as a result of complaints of other users, explant tests, research and other information, that the HiRes 90k devices, and their component parts, were defectively designed and/or manufactured, adulterated, and in violation of federal safety regulations and laws in that they had extremely dangerous properties and defects.

272. Defendants further knew that the devices had a propensity to stop functioning properly and/or completely fail, while implanted, from exposure to moisture and from other causes.

273. At all times relevant to this action, Defendants, despite the actual knowledge described herein above, intentionally suppressed the aforementioned test results, complaints, and other information to keep such knowledge from the general public, including Plaintiffs and Plaintiff's health care providers.

274. Upon information and belief, defendants included a Package Insert with the HiRes90k implanted in Defendant. That insert stated that the device had been exposed to clinical trials. The insert provided graphs and explanations of the failure rate of the device.

275. The clinical trial information provided in the Package Insert related to the HiRes90k with a PA&E feedthru.

276. No clinical trials were performed on the device in the package, namely the HiRes90k with an AstroSeal feedthru.

277. The package label also excluded any reference to the known hazard of leaking through the feedthru.

278. Had Plaintiffs been aware that there was a possibility that the device would leak at the feedthru, or was failing at an alarming rate, Plaintiffs would not have chosen the device.

279. The statements made in the Package Insert were untrue, in that the device enclosed with the insert had not been subjected to any clinical trials, nor were failure rates for any clinical trials known for the HiRes90k with an AstroSeal feedthru.

280. Defendants sent a letter to clinicians on September 27, 2004, informing them of the recall of HiRes90k devices.

281. The September 27, 2004 letter claims that HiRes90k devices have failed and a recall is necessary due to "moisture within devices as they are produced."

282. In reality, the source of moisture in HiRes90k devices was external. HiRes90k devices had a leak path through the defective AstroSeal feedthru, rather than a problem with sealed-in moisture.

283. Prior to September 2004, Advanced Bionics had tested the theory that their manufacturing processes were causing "moisture within the devices as they are produced." Tests had shown that moisture was not being sealed in the devices. Advanced Bionics' Manager of Auditory Quality stated that these tests "lay to rest any concern about the adequacy of the vacuum bake-out conditions to remove liquid water added during the production sequence."

284. Statements in the September 27, 2004 letter regarding the source of moisture and the efficacy of corrective actions being taken by Defendants were false.

285. As a result of Defendants' conduct and Plaintiffs' detrimental reliance on the same, Plaintiff has sustained and will continue to sustain physical injuries, emotional distress, economic losses and other damages for which they are entitled to damages.

286. These damages have been continuing in nature, causing Plaintiffs' injuries, pain and suffering, and economic loss.

COUNT V

CONSUMER FRAUD – VIOLATION OF GBL §§349 AND 350

287. Plaintiffs repeat, reallege and incorporate herein by this reference all of the preceding allegations as though set forth in full.

288. The Defendants acted, used and employed unconscionable commercial practices, deception, fraud, false pretenses, false promises and misrepresentations, and knowingly concealed, suppressed and omitted material facts with the intent that consumers, including the Plaintiff herein and his physicians and medical providers, rely upon such concealment, suppression and omission, in connection with the sale, advertisement and promotion of Defendants' defective Devices, in violation of all applicable state consumer fraud

statutes, for the purpose of influencing and inducing physicians and medical providers to prescribe Defendants' defective Devices to patients/consumers such as the Plaintiff herein. By reason of the Defendants' unconscionable, deceptive and fraudulent acts and practices, and false pretenses, false promises and misrepresentations, reasonable patients/consumers acting reasonably, such as the Plaintiff herein, were caused to suffer ascertainable loss of money and property and actual damages.

289. The Defendants engaged in consumer-oriented, commercial conduct by selling and advertising the subject product.

290. The Defendants misrepresented and omitted material information regarding the subject product by failing to disclose known risks.

291. The Defendants' misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or the knowing concealment, suppression, or omission of material facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of the subject product, in violation of New York General Business Law ("GBL") §§349 and 350.

292. New York has enacted statutes to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. The Defendants violated these statutes by knowingly and falsely representing that the subject product was fit to be used for the purpose for which it was intended, when the Defendants knew it was defective and dangerous, and by other acts alleged herein.

293. The Defendants engaged in the deceptive acts and practices alleged herein in order to sell the subject product to the public, including the Plaintiff herein.

294. As a direct and proximate result of the Defendants' violations of GBL §§349 and 350, the Plaintiff has suffered damages, for which they are entitled to compensatory damages, equitable and declaratory relief, punitive damages, costs and reasonable attorneys' fees.

295. As a direct and proximate result of Defendants' conduct, the Plaintiff used Defendants' defective Devices and the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future, as well as damages for loss of consortium.

296. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for safety and human life, so as to warrant the imposition of punitive damages.

297. The Plaintiff received a HiRes 90k cochlear implant device based on the numerous representations made by the Defendants, including:

a. that the HiRes 90k device was approved by the FDA for use as a cochlear implant;

b. that the HiRes 90k device was safe and effective for use as a cochlear implant;

c. that the HiRes 90k device, including the feed-thru device, was subjected to adequate safety and efficacy testing; and

d. that the HiRes 90k device was expected to last for at least 10 years.

298. These material representations made by Defendants were false as demonstrated by the facts stated above.

299. When the Defendants made these material representations, they knew that they were false, and they made the material representations recklessly without any knowledge of their truth and a positive assertion.

300. The Plaintiffs were induced to use the HiRes 90k device by relying on the statements and representations made by the Defendants that were false, misleading and deceptive in violation of New York law because the cochlear implant was not tested as represented by and did not provide any of the benefits represented by the Defendants.

301. As a result of Defendants' conduct and Plaintiffs' detrimental reliance on the same, Plaintiff has sustained and will continue to sustain physical injuries, emotional distress, economic losses and other damages for which they are entitled to damages.

302. These damages have been continuing in nature, causing Plaintiffs' injuries, pain and suffering, and economic loss.

COUNT VI

BREACH OF EXPRESS WARRANTY

303. Plaintiff readopts and realleges the allegations contained in the preceding paragraphs as though fully set forth herein.

304. Defendants expressly warranted that Defendants' defective Devices were safe and effective devices for those patients requiring a cochlear implant.

305. Defendants' defective Devices manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to the Plaintiff when used as recommended and directed.

306. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

307. Defendants' conduct as described above, including but not limited to its failure to adequately design and manufacture, as well as its continued marketing and distribution of Defendants' defective Devices when it knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

308. These damages have been continuing in nature, causing Plaintiffs' injuries, pain and suffering, and economic loss.

COUNT VII

BREACH OF IMPLIED WARRANTY

309. Plaintiff readopts and realleges the allegations contained in the preceding paragraphs as though fully set forth herein.

310. At the time Defendants designed, manufactured, marketed, sold, and distributed the Defendants' defective Devices for use by the Plaintiff, Defendants knew of the use for which the Defendants' defective Devices were intended and impliedly warranted the product to be of the use for which the Defendants' defective Devices were intended and impliedly warranted the product to be of merchantable quality and safe for such use and that its design, manufacture, labeling, and marketing complied with all applicable federal requirements.

311. The Plaintiff and/or Plaintiff's physicians reasonably relied upon the skill and judgment of Defendants as to whether the Defendants' defective Devices were of merchantable quality and safe for its intended use and upon Defendants' implied warranty as to such matters, including that it was in compliance with all federal requirements.

312. Contrary to such implied warranty, the Defendants' defective Devices were not of merchantable quality or safe for its intended use, because the product was defective as described above, and/or it failed to comply with federal requirements.

313. As a direct and proximate result of Defendants' breach of warranty, the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

314. Defendants' conduct as described above, including but not limited to its failure to adequately design and manufacture, as well as its continued marketing and distribution of the Defendants' Defective Devices when it know or should have known of the serious health risks it created and/or the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

315. These damages have been continuing in nature, causing Plaintiffs' injuries, pain and suffering, and economic loss.

COUNT VIII

NEGLIGENT MISREPRESENTATION

316. Plaintiff readopts and realleges the allegations contained in the preceding paragraphs as though fully set forth herein.

317. In the exercise of reasonable care, Defendants knew or should have known that its Defendants' defective Devices failed to comply with federal requirements for safe design and manufacture and/or was in other ways out of specification, yet Defendants negligently misrepresented the Plaintiff and/or his physicians that its device was safe and met all applicable design and manufacturing requirements.

318. As a result of Defendants' reckless and/or negligent misrepresentations regarding the effects of Defendants' defective Devices, the running statute of limitations has been suspended with respect to claims that Plaintiff has brought or could bring. Plaintiff had no knowledge of Defendants' unlawful conduct, or of any of the facts that might have lead to the discovery of Defendants' wrongdoing, until shortly before this Complaint was filed.

319. The Plaintiff and/or their physicians reasonably relied to their detriment upon Defendants' misrepresentations and omissions in its labeling, advertisements, and promotions concerning the serious risks posed by these products which continue to the present day. The Plaintiff and/or their physicians reasonably relied upon Defendants' representations that Defendants' defective Devices were safe for use.

320. As a direct and proximate result of Defendants' negligent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to its Defendants' defective Devices, Plaintiff used Defendants' defective Devices and Plaintiff suffered serious physical injury, harm, damage and economic loss and will continue to suffer such harm, damages and economic loss in the future.

321. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

322. These damages have been continuing in nature, causing Plaintiffs' injuries, pain and suffering, and economic loss.

COUNT IX

FRAUDULENT MISREPRESENTATION

323. Plaintiff readopts and realleges the allegations contained in the preceding paragraphs as though fully set forth herein.

324. Defendants falsely and fraudulently represented to the medical and healthcare community and to the Plaintiff, and/or the FDA, and the public in general, that the subject product had been tested and was found to be safe and/or effective for hearing loss treatment.

325. The representations made by the Defendants were, in fact, false.

326. When said representations were made by the Defendants, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

327. Defendants knowingly and intentionally made false representations of material fact to Plaintiff, including but not limited to claims that Defendants' defective Devices were safe and effective cochlear implant devices. Defendants specifically marketed the defective devices to doctors treating hearing disabled patients and to patients with hearing disabilities.

328. These representations were made by the Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase the subject device for cochlear implantation in hearing disabled individuals, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff and the public in general.

329. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff was implanted with the Defendants' defective Device, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

330. In reliance upon said representations, Plaintiff was induced to, and did use the subject product, thereby sustaining personal and economic injuries and permanent health consequences requiring revision surgery notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects.

331. Defendants knew and were aware or should have been aware that Defendants' defective device had not been sufficiently tested under actual of simulated use conditions, were defective in nature, and/or that they lacked adequate and/or sufficient warnings.

332. Defendants knew or should have known that Defendants' defective Device had a potential to, could, and would cause injury to the users of said product, were subject to failure requiring removal and replacement surgery, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

333. Defendants brought the subject product to the market, and acted fraudulently, wantonly and maliciously to the detriment of the public including the Plaintiff.

334. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to Defendants' defective Device, the Plaintiff used Defendants' defective Device and the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

335. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

336. These damages have been continuing in nature, causing Plaintiffs' injuries, pain and suffering, and economic loss.

CAUSE X

FRAUDULENT CONCEALMENT

337. Plaintiff readopts and realleges the allegations contained in the preceding paragraphs as though fully set forth herein.

338. At all times during the course of dealing between the Defendants, Plaintiff, Plaintiff's healthcare providers, and/or the FDA, the Defendants misrepresented the safety of Defendants' defective Device for their intended use.

339. Defendants knew or were reckless in not knowing that its representations were false.

340. In representations to Plaintiff, Plaintiff's healthcare providers, and/or the FDA, the Defendants fraudulently concealed and intentionally omitted material information, including but not limited to the fact that:

- the subject product was not as safe as other similar devices and products indicated for cochlear implantation;
- the subject product was defective, and that it caused dangerous side effects, including but not limited to the risks of failure necessitating repeat surgery.
- The subject product was did not include or contain sufficient and/or adequate warnings or labels or instructions.
- the subject product was manufactured negligently;
- the subject product was manufactured defectively;
- the subject product was manufactured improperly;
- the subject product was designed negligently;
- the subject product was designed defectively; and
- the subject product was designed improperly.

341. Defendants were under a duty to disclose to Plaintiff, Plaintiff's healthcare providers, and/or the FDA the defective nature of the subject product, including but not limited to the risk of developing moisture failure, failure and need for revision surgery associated with the use of Defendants' defective Device.

342. Defendants had sole access to material facts concerning the defective nature of the subject product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used Defendants' defective Device, including the Plaintiff in particular.

343. Defendants' concealment and omissions of material facts concerning, *inter alia,* the safety of Defendants' defective Devices were made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff and Plaintiff's physicians, hospitals and healthcare providers into reliance on the use of Defendants' defective devices, and to cause them to purchase, prescribe, dispense, implant and/or use the subject product.

344. Defendants knew that Plaintiff, Plaintiff's healthcare providers, and/or the FDA had no way to determine the truth behind the Defendants' concealment and omissions, as set forth herein.

345. Plaintiff, as well as Plaintiff's doctors, healthcare providers, and/or hospitals, reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by the Defendants.

346. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to its Defendants' defective devices, Plaintiff used Defendants' defective Devices and the Plaintiff suffered injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

347. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

348. These damages have been continuing in nature, causing Plaintiffs' injuries, pain and suffering, and economic loss.

CAUSE XII

LOSS OF CONSORTIUM

349. Plaintiff readopts and realleges the allegations contained in the preceding paragraphs as though fully set forth herein.

350. At all times pertinent hereto, Plaintiff Mattie Evans was and is lawfully married to Plaintiff Monroe Evans, and as such, is entitled to the services, society and companionship of her spouse.

351. As a direct and proximate result of the foregoing, Plaintiff Mattie Evans was deprived of the comfort and enjoyment of the services and society of her spouse, Plaintiff Monroe Evans, has suffered and will continue to suffer economic loss, and has otherwise been emotionally and economically injured. Plaintiff Mattie Evans' injuries and damages are permanent and will continue into the future.

352. These damages have been continuing in nature, causing Plaintiffs' injuries, pain and suffering, and economic loss.

COUNT XIII

PUNITIVE DAMAGES

353. Plaintiffs repeat, reallege and incorporate herein by this reference all of the preceding allegations as though set forth in full.

354. The above-complained of wrongs done by Defendants were aggravated by malice, fraud, and reckless disregard for the rights of others, the public, and Plaintiffs.

355. Defendants were actually, subjectively aware of the risk involved in continuing to market the HiRes 90k device despite having failed to ensure that the Device was hermetically sealed and free of excessive moisture, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of patients, including Plaintiff.

356. Plaintiffs assert claims for exemplary and punitive damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants as follows:

a. For compensatory damages in a sum to compensate Plaintiffs for their damages;

b. For attorney's fees, costs., punitive, and treble damages as permitted by law;

c. For all applicable statutory damages under consumer protection legislation;

d. For prejudgment interest and the costs and expenses of suit; and

e. For such other and further relief as this Court may deem just and proper.

JURY DEMAND

Plaintiffs hereby demand a jury trial on all issues so triable.

DATED: Apr. 2, 2014
Buffalo, New York

Yours, etc.,

CELLINO & BARNES, P.C.

By: _____

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